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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,489	11/03/2003	Gennady Merkulov	CL001103CON	4936
25748	7590	08/09/2006	EXAMINER	
CELERA GENOMICS ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY 45 WEST GUDE DRIVE C2-4#20 ROCKVILLE, MD 20850			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/698,489	Applicant(s) MERKULOV ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

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- 1) Claims 17 to 30 are pending in the instant application.

Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- 3) Claims 17 to 30 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 3 of the office action mailed 23 February of 2006. As stated therein, the instant claims are drawn to an antibody that lacks a specific and substantial utility in currently available form because it is defined solely by the ability to bind to a protein for which a specific biological role has not been disclosed.

Applicant has traversed this rejection on the basis that a protein of the instant invention "belongs to the mitochondrial solute carrier family and the peroxisomal calcium-dependent solute carrier subfamily, is found at the mitochondrial inner membrane, and functions in the transport of metabolites across the membrane" and that Zellweger syndrome and X-linked adrenoleukodystrophy are human metabolic diseases associated with the mitochondrial solute carrier family".

This is not found persuasive. The conclusion that a protein comprising the amino acid sequence presented in SEQ ID NO:2 of the instant application is a member of the mitochondrial solute carrier family has not been disputed. However, one of ordinary skill in the art would not reasonably believe that every member of the mitochondrial solute carrier family is involved in Zellweger syndrome or X-linked adrenoleukodystrophy, and

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there is no evidence of record that, at the time that the instant application was filed, that either of these two disorders was associated with an aberrance in the structure, function or level of expression of a protein comprising the amino acid sequence presented in SEQ ID NO:2 of the instant application.

Applicant appears to of the belief that the assertion that a protein comprising the amino acid sequence presented in SEQ ID NO:2 of the instant application is a member of the mitochondrial solute carrier family constitutes the disclosure of a specific and substantial utility. It does not. Being a member of the mitochondrial solute carrier family is not a utility, it is a property just as being a member of the steroid family was a property of the compound at issue in the decision of *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), and did not constitute an assertion of a specific and substantial use therefor.

Simply disclosing that a particular compound is a member of a recognized family or class of related compounds does not constitute a specific assertion of a substantial utility for that particular compound unless all or most of the members of that class of compounds share a common specific and substantial utility. For example, the disclosure that a particular compound is an antibiotic constitutes an assertion of a specific and substantial utility for that compound because all antibiotics, by definition, have the common utility of selectively inhibiting the growth of certain organisms. Conversely, disclosing that a particular protein is a member of the immunoglobulin family, in the absence of the identification of the particular antigen bound by that protein does not constitute an assertion of a specific and substantial utility for that protein.

To illustrate this point, Example 10 of the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS" (<http://ptoweb.uspto.gov/patents/filecab/documents/Utility.pdf> - 188.0KB, 28 Feb. 2000) explains why a nucleic acid encoding a protein which is structurally related to a well known and commercially useful class of enzymes has specific and substantial utility because that protein is expected to possess those activities that make that class of enzymes commercially valuable. Unfortunately, the proper analysis of the instant claims, which are drawn to an antibody that binds to a putative mitochondrial solute carrier, should be made in light of Example 12 of those guidelines, which explains why an isolated nucleic acid encoding an "orphan receptor" lacks utility in the absence of the disclosure of a specific role for either the nucleic acid or protein in a known disease, disorder or a physiological process which one would wish to manipulate for clinical effect, even though some other members of that receptor family do have a specific and substantial utility. Because most, if not all of the members of the mitochondrial solute carrier family lack a common specific and substantial utility and the instant specification fails to disclose an established practical utility for a protein comprising SEQ ID NO:2 in its currently available form, the claimed antibodies do not meet the "useful" requirement of 35 U.S.C. § 101.

4) Claims 17 to 30 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

5) Claims 18, 20, 22, 24, 26, 28 and 30 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention for those reasons of record in section 5 of the office action mailed 23 February of 2006. As stated therein, because of the presence of the term "wherein the amino acid sequence of said polypeptide **comprises** SEQ ID NO:2", these claims encompass an antibody which binds to an epitope that is not contained within SEQ ID NO:2 and, therefore they essentially encompass any antibody which can bind to any polypeptide or protein.

Applicant has traversed this rejection on the basis that the limitation "that selectively binds to a polypeptide wherein the amino acid sequence of said polypeptide comprises SEQ ID NO:2..." excludes antibodies that do not bind to an epitope contained in SEQ ID NO:2. Applicant's arguments are not persuasive because they clearly ignore the open language Applicant has chosen to use in the instant claims.

6) Claims 18, 20, 22, 24, 26 and 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Hopp et al. patent (5,011,912). As explained above, these claims encompass an antibody which binds to any antigenic peptide, including the flag epitope DYKDDDDK which was bound by the antibody of Hopp et al. prior to the time of the instant invention.

7) Claims 17, 18, 21, 22, 25 and 26 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Weber et al. publication (P.N.A.S. 94:8509-8514, Aug. 1997). Applicant's argument that the polyclonal antibodies of Weber et al. do not bind to a protein of the instant invention are without merit. Because the amino acid sequence of the solute carrier protein of Weber et al. is greater than 95% identical to the amino acid

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sequence presented in SEQ ID NO:2 of the instant application, the **polyclonal** antibodies described in the section entitled “**Immuno-Electron Microscopy**” on page 8510 therein would most certainly be encompassed by the instant claims.

8) Claims 17 to 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over either of the Hopp et al. or Weber et al. publications cited above, each in view of the Maurer et al. publication for those reasons of record.

9) Applicant's arguments filed 23 May of 2006 have been fully considered but they are not persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

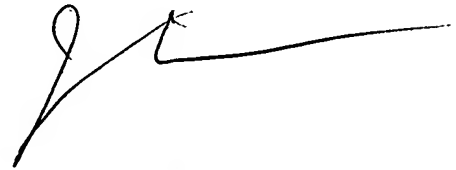
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'J. ULM', with a long horizontal stroke extending to the right.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800